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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,444	08/08/2001	Yi Li	PF116D1C1	9646
22195	7590	12/03/2003	EXAMINER	
HUMAN GENOME SCIENCES INC 9410 KEY WEST AVENUE ROCKVILLE, MD 20850			BRANNOCK, MICHAEL T	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,444

Applicant(s)

LI ET AL.

Examiner

Michael Brannock

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 16 and 30-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 16 and 30-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 12 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 9/12/03, have been entered in full.

Response to Amendment

Applicant is notified that any remaining rejection or objection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments and in view of Applicant's persuasive arguments regarding written description support for human antibodies.

Claims 16 and 30-56 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth previously. The claims are directed to antibodies binding polypeptides of SEQ ID NO: 2. The specification does not appear to assert a use for the antibodies other than in the identification of the polypeptide of SEQ ID NO: 2, e.g. pg 3. Nor does the specification set forth a substantial utility for the polypeptide or the encoding polynucleotides, for the reasons set forth previously.

Applicant asserts that the claimed antibodies can be used as research reagents, i.e. research tools, to, e.g., study the expression patterns of the protein of SEQ ID NO: 2. This argument has been fully considered but not deemed persuasive. As set forth previously, practically every protein has some tissue-specific or temporal pattern of expression, but without some more particular teachings as to how the expression pattern of SEQ ID NO: 2 is important, the artisan would not, therefore, be using the claimed antibodies in anyway other than as a starting point for further research and investigation.

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Applicant argues that it is recognized that research reagents are patentable. This argument has been fully considered but not deemed persuasive. Whatever term is used to describe the claimed antibodies is not relevant to whether or not the antibodies are patentable. The issue is that the specification has not set forth a use for the antibodies that constitutes a substantial utility under 5 U.S.C. § 101.

Claims 16 and 30-51 are also rejected under 35 U.S.C. § 112 first paragraph, as set forth previously. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Applicants' arguments regarding the 35 U.S.C. § 112 rejection as the corollary of the 35 U.S.C. § 101 rejection have been addressed above.

New Rejection:

Claims 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Wadzinski et al., J. Biol. Chem. 267(24)16883-16888, 1992.

The claims do not require that the antibody actually binds to any part of SEQ ID NO: 2, thus there is nothing to distinguish the claimed antibody from that of any other antibody. The specification teaches that a protein comprising SEQ ID NO: 2 and an HA tag was expressed and isolated with an anti-HA antibody pg 25-26.

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Wadzinski et al. disclose an anti-HA monoclonal antibody (12CA5) that binds the HA tag (see the Abstract). Further Wadzinski et al. teach that the antibody was commercially available (col 1 of pg 16884).

Conclusion

No claims are allowable.

Please note the new official fax number below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB


November 25, 2003


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600